K062970

JAN 22 2008

510(k) Summary

Submitted on behalf of: .

Company Name: CU Medical Systems, Inc
Address: Medical Industry Complex, Bldg. No. 2,
1720-26 Taejang-dong,
Wonju-si, Gangwon-do,
220-120 Republic of Korea
Telephone: 8233 747 7657
Fax: 8233 747 7659

by: Elaine Duncan, MS.ME., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **January 15, 2008**

DEVICE TRADE NAME: ***i-PAD NF1200*** Semi-automated External Defibrillator
COMMON NAME: Semi-automated External Defibrillator
CLASSIFICATION NAMES: Low Energy Defibrillator
PRODUCT CODE and REGULATION NUMBER: MKJ, 21 CFR 870.5310 - Automated External Defibrillator

PREDICATE DEVICES:
The ***i-PAD NF1200*** is substantially equivalent to other marketed AEDs in the United States, specifically the following:

Device Name	Manufacturer	510(K) Number
Philips HeartStart OnSite	Philips Medical Systems	K020715
Philips HeartStart FR2+	Philips Medical Systems	K013425
Defibtech Sentry DDU-100A	Defibtech, LLC	K013896

The shock delivered by the device is in the form of a Biphasic Truncated Exponential which has characteristics and results that are substantially equivalent to the cited predicate devices (K013425 and K013896). The operation of this device and its minor differences with the predicate device does not raise new issues regarding safety and efficacy.

DESCRIPTION of the DEVICE:

The ***i-PAD NF1200*** is a semi-automated external defibrillator designed for minimally trained individuals. It provides simple and direct voice prompts and indications for a straightforward rescue operation. The ***i-PAD NF1200*** needs the user to press its SHOCK button to deliver a defibrillating shock.

During a rescue operation, it continuously acquires the electrocardiogram (ECG) of the patient. It also conducts arrhythmia detection continuously except during cardiopulmonary resuscitation (CPR). The timing and duration of the CPR are in accordance with the recommendations of the American Heart Association (AHA) 2005 Guidelines for CPR and Emergency Cardiovascular Care (ECC).

The ***i-PAD NF1200*** is lightweight and battery powered for maximum portability. Its battery pack has a capacity of 200 shocks (10 hours of operating time.)

It delivers a 150-Joule biphasic truncated exponential shock waveform that it compensates for patient impedance by adjusting its timing parameter. If the user decides not to deliver a charge, the ***i-PAD NF1200*** disarms itself by dumping the charge into an internal resistive load.

The ***i-PAD NF1200*** is capable of saving data and transmitting them to an external device.

The ***i-PAD NF1200*** conducts periodic (daily, weekly, and 28-day) self-tests, a battery insertion self-test, and self-tests during power-ON and run-time. It informs the user if an error is detected through audio and visual indicators.

Indications for Use

The ***i-PAD NF1200*** is used to treat a person suffering from sudden cardiac arrest (SCA) and who exhibits symptoms of

- No movement and no response when shaken
- No normal breathing

Contraindication for Use

The device must not be used on a person who:

- Is moving or is responsive when shaken
- Is breathing normally

Target Patients

- Adults
- Children over 55 lbs or 8 years old
- The device is not to be used on children below 8 years old or under 55 lbs

Intended User

The device is intended for use by persons:

- who have been specifically trained in its operation.
- who have training in cardiopulmonary resuscitation (CPR) or other physician-authorized emergency medical response program in accordance with local and state requirements

COMPARISON OF TECHNOLOGY CHARACTERISTICS

The ***i-PAD NF1200*** employs the same fundamental technological characteristics as the predicate devices. Differences in implementation are verified and validated using relevant test protocols.

SUMMARY of TESTING:

Shock Waveform Effectiveness and Safety

Substantial equivalence with the predicate device is shown by bench testing. The submission device and the predicate device are discharged and the shock waveform parameters are captured using an oscilloscope with energy measurement capability.

Statistical analysis is used to show that the mean values of the shock waveform parameters of the ***i-PAD NF1200*** are closer to the mean values of the shock waveform parameters of the ***Philips HeartStart FR2+*** than the mean values of the ***Defibtech DDU-100A*** shock waveform parameters.

Arrhythmia Detection Algorithm

The arrhythmia detection algorithm is tested using the recommendations of the American Heart Association and the ANSI/AAMI DF80 Standard.

Electrical Safety and Compliance to Defibrillator Standard

The ***i-PAD NF1200*** was tested using EN60601-1 and EN60601-2-4. The EN60601-2-4 has the same contents as the ANSI/AAMI DF80 Standard except for some additional sections in the ANSI/AAMI DF80 regarding Defibrillator Electrodes and External Pacing.

CONCLUSION

The ***i-PAD NF1200*** is substantially equivalent to its predicate devices. Testing shows that the submission device does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2008

CU Medical Systems, Inc
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082

Re: K062970
Trade/Device Name: I-Pad NF1200 Semi-Automated External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: November 28, 2007
Received: November 29, 2007

Dear Ms Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: i-PAD NF1200

Indications For Use:

The i-PAD NF1200 is used to treat a person suffering from sudden cardiac arrest (SCA) and who exhibits symptoms of

- **No movement and no response when shaken**
- **No normal breathing**

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062970